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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation, LISA HYDE and MARK HYDE, a married couple, Plaintiffs, v. C. R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, Defendants.	No. 2:15-MD-02641-DGC **DEFENDANTS' MOTION AND MEMORANDUM IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT AS TO PLAINTIFFS LISA AND MARK HYDE'S CLAIMS** (Assigned to the Honorable David G. Campbell)

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Pursuant to Fed. R. Civ. P. 56(c), Local Rule 56.1(a), and Case Management Order No. 53 (Doc. 5770), Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard") respectfully submit this Separate Statement of Facts in Support of its Motion for Partial Summary Judgment as to Plaintiffs Lisa and Mark Hyde's Claims.

1. [redacted] (Ex. A, Plaintiffs' Fact Sheet ("PFS") at § II.3.; Ex. B, Selected Plaintiff Medical Records at HYDEL_WFHW_MDR00099.)

2. The plaintiffs were Wisconsin residents at that time. (Ex A, PFS at § I.5.)

3. [redacted] (Ex. A, PFS, at §§ II.2(a), II.4, II.5.; Ex. B, Selected Plaintiff Medical Records at HYDEL_WFHF_RAD00002 - HYDEL_WFHF_RAD00003.)

4. At the time of Ms. Hyde's filter implant, Dr. Henry was only practicing medicine in Wisconsin. (Ex. C, April 6, 2017 Dr. David Henry Deposition Transcript ("Henry Dep. Tr.") at 4:23-5:2, 22:16-20.)

5. Any contacts Bard had with Dr. Henry would have occurred in Wisconsin through Bard's Wisconsin-based sales representative, Matthew Fermanich. (Ex. D, March 27, 2017 Matthew Fermanich Deposition Transcript at 17:1-18:19.)

6. Nothing in the record indicates what, if any, changes occurred to the Bard filter from the time that it left Bard's possession to the time that it was placed in Ms. Hyde.

7. Dr. Henry testified that the Bard filter's ability to "potentially be retrieved" was "definitely" one of the benefits that he considered in choosing the Bard filter for Ms. Hyde. (Ex. C, Henry Dep. Tr. at 89:25-90:12.)

8. In 2001, the Society of Interventional Radiology published the following clinical practice guidelines that reported about the complications of all IVC filters. (Ex. E, Grassi, *Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena*

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Cava Filter Placement for the Prevention of Pulmonary Embolism, 12 J. Vascular & Interventional Radiology 137, 139 (2001).)

9. The Society of Interventional Radiology reported that IVC filters migrate (reported at rates up to 18%), fracture (reported at rates up to 10%), perforate the IVC (reported at rates up to 41%), and tilt (reported at rates from 5 to 50%). *Id.*

10. In 2009, *Binkert, et al.* published a study in the Journal of Vascular and Interventional Radiology 2009 reporting on perforation, filter fracture, tilt, and migration with Bard's filters. (Ex. F, Binkert, C.A., *et al.*, *Technical Success and Safety of Retrieval of the G2 Filter in a Prospective, Multicenter Study*, J VASC. INTERV. RADIOL. 2009; 20:1449-1453.)

11. On August 9, 2010, the FDA issued a Safety Alert concerning all IVC filters. (Ex. G, *Inferior Vena Cava (IVC) Filters: Initial Communication: Risk of Adverse Events With Long Term Use*.)

12. The FDA wrote, "Known long term risks associated with IVC filters include but are not limited to lower limb deep vein thrombosis (DVT), filter fracture, filter migration, filter embolization and IVC perforation." *Id.*

13. Also in 2010, Dr. Nicholson, *et al.* authored a published article reporting on perforation, filter fracture, tilt, and migration with Bard's filters. (Ex. H, Nicholson, *et al.*, *Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cava Filters and Clinical Implications Including Cardiac Perforation and Tamponade*," ARCHIVES OF INTERNAL MEDICINE, Vol. 170 No. 20, November 8, 2010.)

14. Dr. Henry testified that at the time of Ms. Hyde's implant he was aware that IVC filters in general could move, fracture, and that fractured components could embolize. (Exhibit C, Henry Dep. Tr. at 85:17-87:10.)

15. Dr. Henry also testified that his criteria for choosing an IVC filter for Ms. Hyde was that it is cleared for use by the FDA, that he trusts the FDA more than individual manufacturers, and that he would not have altered his treatment of Ms. Hyde with a Bard IVC filter even if he was provided with certain facts the plaintiffs allege to be

true. *Id.* at 25:13-25, 31:15-32:11, 44:20-45:24.

16. Dr. Henry further testified that he did not recall any discussions with Bard's sales representatives that occurred at any time before treating Ms. Hyde. *Id.* at 39:14-40:8.

17. The IVC filter implanted in Ms. Hyde was sold by Bard to Wheaton Franciscan Healthcare Hospital.

18. The IVC filter implanted in Ms. Hyde is not sold directly to patients. (Ex. I, G2®X Instructions for Use (the "G2X IFU") at page 1; Ex. J, Eclipse® Filter Instructions for Use (the "Eclipse IFU") at page 1.)

19. The G2X and Eclipse® IFU applicable in February 2011 (when the plaintiff received her Filter) included the following identical warnings:

a. Under the bolded headings "**Warnings**" and "**Potential Complications**," the IFUs warn of the following complications, which may occur at any time during or after the procedure:

- Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.

- Movement, migration or tilt of the filter are known complications of vena cava filters. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots, and/or dislodgement due to large clot burdens.

(Ex. I, G2X IFU, Ex . J, Eclipse IFU.)

20. The "**Potential Complications**" of the IFUs also warn about "Filter tilt," "Filter malposition," "Perforation or other acute or chronic damage of the IVC wall, and "Vessel injury." *Id.*

21. Finally, the IFUs also warn that "**All of the above complications may be associated with serious adverse events such as medical intervention and/or death.**"

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Id.

22. The plaintiffs have not identified alternative warnings that would have rendered Bard's IVC filter safe.

23. The plaintiffs' expert, Dr. Derek Muehrcke, acknowledges that all IVC filters are known to have complications, including filter fracture, migration, tilt, penetration, and perforation. (Ex. K, July 24, 2017 Dr. Derek Muehrcke Deposition Transcript at 55:22-57:9.)

24. Bard is not aware of any IVC filter manufacturer that provides comparative rates in the instructions for use that it provides to doctors.

25. Bard's G2X and Eclipse IVC filters were cleared for use by the FDA through its 510(k) process. (Ex. L, FDA Clearance Letter for G2X IVC filter, Ex. M, FDA Clearance Letter for Eclipse IVC filter.)

26. As part of Bard's compliance with the FDA's 510(k) process, Bard submitted proposed warnings for the G2X and Eclipse filters, which were approved by the FDA as part of the FDA's clearance of the devices. (*See* Exhibit 104 to Robert Carr's Declaration in Support of Bard's Motion for Summary Judgment Regarding Preemption at BPV-17-01-130627 – BPV-17-01-130660, lodged under seal at docket no. 5411; Exhibit 121 to Robert Carr's Declaration in Support of Bard's Motion for Summary Judgment Regarding Preemption at BPV-17-01-00117076 – BPV-17-01-00117095, lodged under seal at docket no. 5411.)

27. Neither of the plaintiffs have ever spoken to anyone at Bard or received any information from Bard. (Ex. N, January 25, 2017 Lisa Hyde Deposition Transcript (Lisa Hyde Dep. Tr.") at 140:13-22.; Ex. O, January 25, 2017 Mark Hyde Deposition Transcript at 48:22-49:1.)

28. On May 16, 2014, while the plaintiffs were residents of Nevada, Ms. Hyde first learned that her IVC filter had fractured. (Ex A, PFS at I.5, II.12(iii).)

29. The plaintiffs have not identified a reasonable alternative design to Bard's IVC filter that would have reduced or avoided risks of harm that Ms. Hyde experienced

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while also retaining the option of percutaneous retrieval.

30. The plaintiffs moved from Wisconsin to Nevada because of Mark Hyde's employment. (Ex. N, Lisa Hyde Dep. Tr. at 18:20-19:2.)

31. Ms. Hyde's IVC filter and fractured strut were removed percutaneously in California. (Ex A, PFS at II.10(a)-(c).)

32. The plaintiffs' expert, Robert M. McMeeking, Ph.D., acknowledges that the Simon Nitinol Filter does not represent a reasonable alternative design to Bard's retrievable IVC filters. (Ex. P, July 6, 2017 Robert M. McMeeking, Ph.D. Deposition Transcript at 221:16-223:3.)

RESPECTFULLY SUBMITTED this 28th day of August, 2017.

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CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of August 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
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